FOREWORD:

E-HEALTH: PERSPECTIVE AND PROMISE

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Historically, and without controversy, e-health first emerged in the guise of "telemedicine." Popular among physicians seeking consultations and populist in its focus, telemedicine has delivered mental health and other medical services to rural and other underserved communities for three decades.[1] Its frequent state sponsorship and typically intrastate reach shielded it from legal or ethical scrutiny. Mainstream health care institutions, however, did little to expand on telemedicine. While Web and other information technologies (IT) prospered in other industries, technologically-mediated care displayed little traction.

Not surprisingly, given the absence of a sound health care delivery IT infrastructure that could be leveraged, the second wave of e-health owed little to traditional health care. Instead, the dot.com revolution made venture capital available to innovators outside of traditional health care and focused our attention on innovative structures for health care delivery that were designed to supplement or even compete with traditional health care.[2] In the words of Paul Starr, "on a separate track that the industry hardly thought worth its attention, popular health communication on the Internet was exploding . . . ."[3] Observing the structural effects involved, Starr continues, "the 'system' is coming to the 'people' as health plans and providers establish Web sites and open up online avenues of communication with patients and each other."[4] True to its relatively pure e-commerce roots, the second wave of e-health was most

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1. *See generally* The University of Arizona Health Sciences Center, *Rare Glimpse at the Early Days of Telemedicine: Arizona Health Sciences Library, Arizona Telemedicine Program Joins Forces to Preserve Early Telemedicine Archive* (Sept. 20, 2001), *at* http://www.ahsc.arizona.edu/opa/news/sep01/telemed.htm (last visited Jan. 4, 2002).

2. *See* Nicolas P. Terry, *Structural and Legal Implications of E-health*, 33 J. HEALTH L. 606 (2000).

3. Paul Starr, *Health Care Reform and the New Economy*, 19 HEALTH AFFAIRS 23, 28 (2000).

4. *Id.*

notable for its business-to-consumer (hereinafter referred to as "B2C") models. Among the e-health services that arose, the most common business model was the health information Web site, exemplified by the dominant player WebMD.[5] Other online e-health business models are more controversial, ranging from sites that sell or broker health insurance,[6] services that match patients to clinical trials,[7] treatment auctions[8] and even the leading medical associations' Medem service.[9] Legal analysis of these early manifestations of e-health focused on their legality, given our state-centric licensure and disciplinary systems,[10] and examined the quality assurance issues[11] raised by the sometimes dubious information found on an apparently ever-expanding number of health-related Web sites.[12]

Recently, and coincident with the dot.com implosion, the analytical focus has shifted to business-to-business (hereinafter referred to as "B2B") e-health. This third wave of e-health has moved swiftly beyond the realm of B2C models to increasingly robust B2B services and transactions such as continuing medical education, publishing and procurement. Many of the possible legal implications are quite challenging: Will medical diagnosis and monitoring appliances be characterized as "products" or "services" for liability purposes? What are the legal effects of more aggressive marketing-led Web-presences of health care entities[13] and pharmaceutical companies?[14]

The fourth, and at this writing, rapidly emerging iteration of e-health sees technologically-mediated care less as a goal in and of itself (as was the case with, for example, health advice on the Internet), but as a method of solving severe and pressing issues in traditional health care: spiraling health care costs and medical error. The Department of Health and Human Services is in the process of promulgating regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to accelerate the adoption of e-commerce

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5. *See* WebMD, *at* http://www.WebMD.com (last visited Jan. 4, 2002).

6. *See* eHealthInsurance.com, *at* http://www.ehealthinsurance.com/ehi/index.html (last visited Jan. 4, 2002).

7. *See* Acurian, *at* http://www.acurian.com/ (last visited Jan. 4, 2002).

8. *See* MedicineOnline.com, *at* http://www.medicineonline.com/bidforsurgery/ (last visited Jan. 4, 2002).

9. *See* Medem, *at* http://www.medem.com (last visited Jan. 4, 2002).

10. *See, e.g.*, Ross D. Silverman, *Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards*, 26 AM. J.L. & MED. 255 (2000).

11. *See generally* Nicolas P. Terry, *Cyber-Malpractice: Legal Exposure for Cybermedicine*, 25 AM. J.L. & MED. 327 (1999).

12. *See generally* Gretchen K. Berland et al., *Health Information on the Internet: Accessibility, Quality, and Readability in English and Spanish*, 285 JAMA 2612 (2001).

13. Kashishian v. Port, 481 N.W.2d 277, 282 (Wis. 1992), *discussed in* Nicolas Terry, *When the "Machine That Goes 'Ping'" Causes Harm: Default Torts Rules and Technologically-Mediated Health Care Injuries*, 46 ST. LOUIS U. L.J. 37 (2002).

14. *See, e.g.*, Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1263 (N.J. 1999).

systems throughout the health care industry, specifically to ensure the use of Electronic Data Interchange (EDI) for most health care transactions. As a result, complex legal questions are developing as traditional (or bricks-and-mortar) health care providers introduce heretofore unheard of amounts of technology into their "backend" or administrative services such as billing, insurance reimbursement and prescription fulfillment systems.

Here, the most pressing legal issue concerns the privacy of medical records. EDI creates severe privacy externalities that HIPAA's *Standards for Privacy of Individually Identifiable Health Information*[15] valiantly attempt to address. Those privacy regulations themselves raise challenging legal issues because of their inherent complexity and uncertain relationship with state privacy protections. The HIPAA privacy regulations frequently do not apply to some important entities such as life insurers or popular business models such as health care Web sites.[16]

As I have argued, "[t]he technology that directly or indirectly is required by the architecture of [HIPAA] will hasten, even jump-start, process reform and the development of the overall health care information infrastructure. In addition, it will accelerate the acceptance of technological solutions by healthcare professionals, hastening technologically-mediated quality improvement."[17] Although a latecomer to the health care industry, high technology (particularly information technology systems and their networked point-of-treatment appliances) is widely viewed as the key element in the search for reduced medical error.

Meanwhile, as e-health in the United States undergoes its own growing pains, we must not lose sight of the subject's global importance. United States health lawyers view e-health as an essentially private business model, and in its most obvious dot.com forms an aggressively entrepreneurial one. However, the humble telemedicine roots of e-health have tended to direct its growth outside of the United States, no doubt aided by the *public* nature of non-United States health care delivery. In many countries e-health is the solution to bringing health care to underserved populations or geographic areas.

Watershed developments afford us with excellent opportunities to reexamine our legal and ethical structures. The growth of e-health suggests a compelling opportunity to examine some of our core tenets given the perspective provided by new business models or technologies and novel

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15. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (proposed Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160 & 164).

16. *See, e.g.*, Health Privacy Project, Institute for Health Care Research and Policy, *Exposed Online: Why the new federal health privacy regulation doesn't offer much protection to Internet users* (Nov. 2001), *at* http://www.pewinternet.org/reports/pdfs/PIP_HPP_HealthPriv_report.pdf (last visited Jan 4, 2001).

17. Nicolas P. Terry, *An eHealth Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation*, 27 AM. J.L. & MED. 361, 373 (2001).

patient interactions with health care professionals and institutions. Entitled "E-health: structural, legal and ethical implications," Saint Louis University's 13th Annual Law Journal Health Law Symposium was held April 20, 2001. The opportunity to discuss the next wave of health law issues engendered by the technological advances surrounding us was grasped eagerly by some of today's most innovative and influential thinkers. On behalf of the School of Law and the *Saint Louis University Law Journal*, I thank Skip Rosoff, Jessica Berg, John Blum, Richard Cleland, Larry Gostin and Audiey Kao for their participation in our conference and this Symposium publication. I also take this opportunity to thank Aaron Pawlitz, the *Law Journal's* Editor-in-Chief, and Christina Bahr, the Health Law Symposium Editor, for their skillful and patient work.